

POSTSCRIPTS

In this issue

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- The Cox Model
- Tracking Changes in Word
- Special Reports from Bethesda
 - AMWA Board of Directors' Meeting
 - Medical Communications Inter-organizational Summit

POSTSCRIPTS

AIMS AND SCOPE

Postscripts is the newsmagazine of the American Medical Writers Association Pacific-Southwest (AMWA Pac-SW) chapter. It publishes news, notices and authoritative articles of interest in all areas of medical and scientific writing and communications. The scope covers clinical/regulatory writing, scientific writing, publication planning, social media, current regulations, ethical issues, and good writing techniques.

MISSION STATEMENT

The mission of *Postscripts* is to facilitate the professional development of medical writers and serve as a tool to advance networking and mentoring opportunities among all members. Towards this mission, *Postscripts* publishes significant advances in issues, regulations and practice of medical writing and communications; skills and language; summaries and reports of meetings and symposia; book and journal summaries. Additionally, to promote career and networking needs of the members, *Postscripts* includes news and event notices covering Chapter activities.

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SUBSCRIPTION

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INSTRUCTION FOR CONTRIBUTORS

We welcome contributions from members and non-members alike. Please contact editor.

ADVERTISING

Articles describing products and services relevant to medical writers may be considered or solicited. Members may submit advertisements for their services or products for free. Please contact editor for details.

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UPCOMING EVENTS AND DATES

May 16, 2014. Friday, 11:30AM. **Lone Writer Lunch** at Karl Strauss, La Jolla. RSVP kmoore@reactiondesign.com

May 20, 2014, Tuesday, 5:30-7:30 pm. **Medical Writer Happy Hour at Casa de Bandini (South Carlsbad).** No RSVP required. Questions please contact president@amwa-pacsw.org

Enrollment open for UCSD Extension course “Science Writing” by Lynne Friedman, editor of ScienceWriters Magazine and fellow of American Association for the Advancement of Science. Course dates: **Oct 1-Dec 3, 2014** (Wednesdays. 6:30-9:30 PM). <http://extension.ucsd.edu/studyarea/index.cfm?vCourse=WCWP-40105>

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From the President's Desk

—Among the changing months, May stands confess
The sweetest and in fairest colors dressed.

James Thomson

Happy start to May!
We hope you are having a wonderful Spring.

April was a busy month for our chapter. Earlier in the month, our fellow Arizona colleagues engaged in delightful conversation at a social brunch in Phoenix. We thank our chapter delegate, Kathy Boltz, for attending the AMWA Spring Board of Directors Meeting on our behalf. A few of us from our chapter attended the International Society of Medical Publication Professionals (ISMP) meeting that took place among the cherry blossoms in Arlington.

Speaking of conferences, did you attend the Pacific Coast Conference in Asilomar, CA? We would love to hear about your experiences there. Please feel free to email us your pictures and/or stories and we can consider adding them to our conference summary in the June issue.

We thank Wilm D'Haeze, Sally Altman, Dikran Torosser and Susan Chang for keeping us updated about recent regulatory news, explaining complex statistical models and showing us how to redline Word documents.

We have more to make you smile in this issue. Lanie Adamson's amusing stories give a personal example of how to write humor. Irene Yau takes us on a tour of three remarkable European cities: Munich, Paris and London.

More events are being planned in other chapter locations including joint meetings with other societies so stayed tuned!

Donna

Donna Simcoe, MS, MS, MBA, CMPP
President, AMWA Pacific Southwest Chapter

AMWA Pacific-Southwest Chapter warmly
welcomes our new members

Udeme Asuamah - San Mateo, CA

Jennifer Shepphird - Hermosa Beach, CA

Doug Frankel - Carlsbad, CA

Julie Farley - San Diego, CA

Heather Javier - Burbank, CA

Leila Abours - Temecula, CA



HOME



Europe – Three Remarkable Cities

By Irene Yau, PhD, Allergan

My husband and I had the opportunity to visit Europe in March. The cities I visited gave me a deeper appreciation for European history, public transportation, and good food.

MUNICH, GERMANY

Neuschwanstein

The original Sleeping Beauty's castle, Neuschwanstein towers up on the hills. King Ludwig II commissioned this castle. He was also hopelessly fixated on the centuries that came before his time, which is why although the architecture would indicate the Middle Ages, Neuschwanstein was actually built in the middle of the 1800's (construction started in 1869 but the inside was never completely finished). This castle would become the inspiration for Disney's Sleeping Beauty Castle. A 30-minute hike took us to the castle, but the optional 10-minute additional hike uphill was the real hidden gem – a spot on the suspension bridge that allowed us to take the postcard-like photo of the castle (Cover Photo)

BMW Factory Tour

We reserved tickets ahead of time for a tour of the BMW Factory. It was amazing touring the factory, seeing first hand German engineering at its finest. There were dozens of machines – machine to paint

the cars, machines to screw in the bolts, machines in training, machines in time out, and my favorite, machines that check the work of other machines! Unfortunately, photos were not allowed...and unfortunately, we did not drive one of these babies back home.

We rode the overnight Bahn to Paris, France. The overnight sleeper cart was an exciting experience with tight sleeping quarters, but smartly laid out. Our train from Munich originally had half the train cars headed to Amsterdam, and the other half headed to Paris. When we woke up in the morning, the train carts had rearranged and merged like Legos® throughout the night and arrived at their correct destination – don't get on the wrong cart is an understatement!





PARIS, FRANCE

The city of lights, the city of romance, the city of art - there are numerous names for this special city and they are all fitting! I did fall in love with Paris and its sights, musicians, museums, and of course, its food (Photo, previous page) We had a solid 5 days in this city to relax, enjoy the city, and enjoy life much like the French do! Of course we visited the Eiffel tower during the day and night to enjoy the two different views (Photo, right), visited the museums like the Louvre (Photo, below), and the parks. My favorite memory was leisurely eating outdoors at a café watching the Parisians (and tourists) walking about. The waiter did not rush us out and we did not have anywhere we needed to be. One custom I learned when dining out is that the complimentary bread is eaten off of the table rather than off of the plate. (Photo, below)



A little ways out of Paris is the Palace of Versailles – the epitome of extravagance and indulgence. It started as a small hunting lodge by King Louis XIII and was transformed into a palace by King Louis XIV with subsequent expansions from the next two generations. Some say the palace represents absolute monarchy, which is what King Ludwig II had always pined after. (Banner Photo)





LONDON, ENGLAND

Our last destination was London. We took a walking tour to observe the changing of the guards, which begins at St. James Palace where the fresh guards march to Buckingham palace. We learned that the large black domed hats are made out of Canadian bear fur and can weigh up to 1.5 pounds (Photo, top). Another highlight was visiting the British National Museum, which is free, and houses treasures and artifacts such as the Rosetta Stone, and taking an afternoon tea break on the top level. We also visited the lesser-known London Transport Museum that explained the history of London transportation from the trains to the double deck buses. The original "bus" involved a horse and carriage. After a while, someone observed that the space above the horse carriage has room for a few more paying customers. Railings and a covering were added to the top level and eventually led to the emergence of the double decker bus. (Photos, right)



How to Write Humor: Is it Real or is it Comedy?

By Lanie M Adamson, MS

I had mixed emotions after our youngest daughter's wedding. On one hand, it went off almost entirely as planned. On the other hand, I expected to have some comedy material for an upcoming Toastmasters contest and was rather empty-handed.

The material was there. It just needed some creative editing. Here are the before and after versions of one story in "A Simple Wedding." The after version shows the setup lines (S) and punch lines (P). The talk was a hit.

The Ring Bearer - Before

The wedding took place outdoors in the late afternoon of a hot July day in the central coast of California. Fifteen minutes after the wedding was to start, the guests were seated in the hot sun and fanning themselves. Finally the wedding party lined up and the guitarist began to play. The bridesmaids and groomsmen took their places on either side of a gazebo garlanded with roses. The ring bearer had had enough of waiting and he stomped his way down the red carpet. Then he ran to his mother, one of the bridesmaids.

The Ring Bearer - After

S: It was an outdoor wedding on the hottest day in 10 years on the central California coast. Wood chairs were lined up in front of a large gazebo decorated with pink and white roses. The guests took their chairs and fanned themselves.

S: Fifteen minutes after the appointed time, the guitarist signaled the start of the wedding. The bridesmaids strode gracefully to the altar on the arms of the groomsmen. The minister and groom moved into their positions. Just like rehearsal.

S: The ring bearer, our 6-year-old grandson, wore a tuxedo and a scowl. His job was to ring a bell to announce the bride, but he was fed up from waiting.

S: He sulked and stomped all the way down the red carpet to the altar.

P-1: Where he tripped over a bridesmaid.

S-2 Fortunately, we didn't have to worry about losing the rings.

P-2 The bride and groom had tattoos.

My technique is to write down a story or a few lines from an event to capture it on paper. I let everything flow onto the paper without worrying about grammar, punctuation or spelling. I capture visual elements that bring the scene to life: weather (guests fanning themselves), location (central California coast) and mood (bridesmaids strode gracefully, our grandson wore a tuxedo and a scowl). I save this version as source material and then “Save As” the spoken version, which will be heavily trimmed.

I write out the spoken version in the setup and punch line format shown above, a technique I learned from comedian Steve Roye. It’s easy to read and memorize. Next I concentrate on what will get laughs. It took several rewrites before the ring bearer tripped over the bridesmaid. When I had that image, I knew it was right.

And sometimes you don’t need to change a thing:

S: At the reception, it was time for the toast.

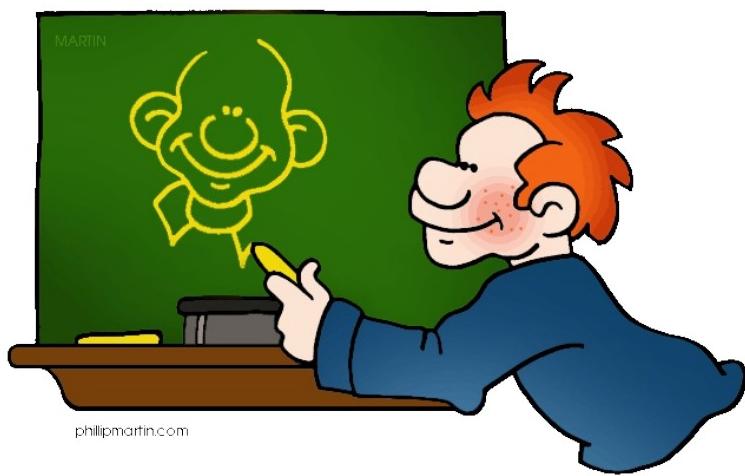
S: The Father of the Bride raised his glass. “As we were preparing for this wedding, I asked a friend of mine – who had married off 5 daughters – for his advice.”

P: He said, “Show up, shut up and pay up!”

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This article was first published in 2006 at Lanie Adamson's website, www.lanieadamson.com. Lanie is an AMWA Fellow and a long-time member of the Pacific Southwest Chapter. Now retired, she can be reached at lanieadamson@gmail.com.

—Editor



The Buzz from Bethesda: AMWA Spring Board of Directors Meeting

By Kathy Boltz, PhD

AMWA members have spoken, and AMWA is moving forward to implement more online learning opportunities. This multi-step process will involve choosing infrastructure that can handle all online learning. It will result in increased educational offerings from AMWA. That was part of the exciting news from the 2014 Spring AMWA Board of Directors Meeting, held April 11-12 in Bethesda, Maryland.

The annual conference schedule will be a little different from years past. Two award presentations will bookend the conference. The Sablack Awards will be presented at a free lunch, so all AMWA members can come and listen to the winner of our most prestigious award.

Roundtable leaders are still needed for the conference. If you are interested in presenting one, email annual_conference@amwa.org ASAP.

The medical writer certification is moving forward, with the first exam expected to occur at the 2015 Annual Conference. Also, 2015 marks the 75th anniversary of AMWA.

The AMWA board of directors discussed a planned nondiscrimination policy. AMWA's president, Brian Bass, noted that AMWA has never had a problem in the past, but that the organization wanted to adopt an official policy. The policy will now go to AMWA's attorney for feedback, and it will be presented to the board for a vote at the fall meeting.

Leading Medical Communications Industry Organizations Recognize Synergies, Discuss Opportunities and Challenges

On April 10, 2014, leaders of the American Medical Writers Association, the Drug Information Association (DIA), the International Society for Medical Publication Professionals (ISMP), and the Society for Technical Communication (STC) met in Bethesda, MD, for the first-ever Medical Communications Inter-organizational Summit. The purposes of the Summit were to recognize the many similarities among the respective organizations; explore synergies that might benefit the organizations and their members; discuss challenges facing the medical communications industry, the organizations, and their members; and identify opportunities to share resources and experiences that can strengthen the organizations, benefit their members, and serve their missions.

The participating organizations share certain core beliefs: commitment to integrity for the medical communications field, and to being leaders in promoting excellence – both within the industry and to their members – by providing guidance and continuing education. All of the participating organizations are non-profit, membership-based organizations. They are rich in educational resources and content, and their members are collectively involved in all aspects of medical communications.

Summit participants were particularly interested in exploring how to share educational resources, capitalize on the use of social media to further their missions, and advocate for best practices and industry standards that uphold their common commitments to integrity and excellence. They agreed to reconvene via scheduled teleconferences in the near future to address these and other topics warranting deeper discussion.

Brian

**Brian Bass
President, AMWA**

Medical Communications Inter-organizational Summit delegates



Picture courtesy of Brian Bass

What's Up(!) . . . at EMA

By Wim D'Haeze, PhD, Arena Pharmaceuticals, Inc.

EUROPEAN MEDICINES AGENCY (EMA) ALERTS (29 MAR 2014 THROUGH 26 APR 2014)

The alerts listed below cover the period from March 29, 2014 through April 26, 2014. Only key alerts thought to be of interest to the AMWA community were included; for additional updates and details refer to What's New on the EMA website.

GUIDELINES

- Draft concept paper on the establishment of a guideline on the selection of sterilisation processes for drug products (open for publication consultation)^a

REPORTS/PAPERS

- None to report

APPROVALS/REFUSALS

| Compound | Indication/Use | Applicant | Advice [Note] |
|-----------------------|---|------------------|------------------|
| Mekinist ^b | Treatment of adult patients with unresectable or metastatic melanoma with a BRAF V600 mutation; no clinical activity has been demonstrated in patients who have progressed on a prior BRAF inhibitor therapy. | Glaxo Group Ltd. | Positive opinion |

Note: "positive" or "negative" opinion indicates the Committee for Medicinal Products for Human Use (CHMP) adopted a positive or negative opinion in regards of granting the marketing authorization, respectively, awaiting a final decision of the European Commission (EC).

GENERAL ANNOUNCEMENTS

- EC/EMA-FDA bilateral - update.^c

EMA Website - What's New:

http://www.ema.europa.eu/ema/index.jsp?curl=pages/news_and_events/landing/whats_new.jsp&mid=WC0b01ac058004d5c4 [[Link](#)]

^ahttp://www.ema.europa.eu/ema/doc_index.jsp?curl=pages/includes/document/document_detail.jsp?webContentId=WC500164971&murl=menus/document_library/document_library.jsp&mid=0b01ac058009a3dc [[Link](#)]

^bhttp://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002643/smops/Positive/human_smop_000675.jsp&mid=WC0b01ac058001d127 [[Link](#)]

^chttp://www.ema.europa.eu/ema/index.jsp?curl=pages/news_and_events/news/2014/04/news_detail_002078.jsp&mid=WC0b01ac058004d5c1 [[Link](#)]



During the month of April, there were a number of voluntary drug recalls, the primary reasons for which were visible particulate matter and undeclared ingredients. The FDA announced changes in label requirements to address concerns about the efficacy and safety of epidural corticosteroid injections to treat certain kinds of pain. In addition, the agency approved several new drugs with indications including improved glycemic control, advanced gastric cancer or gastro-esophageal junction adenocarcinoma, multicentric Castleman's disease, and anaplastic lymphoma kinase-positive metastatic non-small cell lung cancer.

Selected FDA Announcements

- 4-1-14 Nova Products, Inc. issued a voluntary recall of dietary supplements containing undeclared active pharmaceutical ingredients.¹ The Pennsylvania company issued the recall after some lots of its African Black Ant™, Black Ant™, XZen Gold™, ZXen Platinum™, XZen 1200™, XZone Gold™, XZone 1200™, and Mojo Risen™ products were determined to contain undeclared sildenafil and tadalafil, which are active ingredients in drugs indicated in the treatment of erectile dysfunction. Each of the recalled products is sold as a dietary supplement indicated for sexual enhancement.
- 4-9-14 Nature's Universe issued a voluntary recall of all Thinogenics™ weight loss products sold before February 6, 2014 following the discovery of undeclared sibutramine during FDA analysis.² Sibutramine, an appetite suppressant, was withdrawn from the U.S. market in October 2010 because it may increase blood pressure and pulse rate in some patients and it is associated with an increased risk of seizure, heart attack, arrhythmia, and stroke.
- 4-10-14 The FDA advised consumers not to use two other weight loss products, Infinity™ and Lite Fit USA™, after FDA analysis determined that these products also contained undeclared sibutramine.^{3,4} The agency issued a public warning about increasing occurrences of undeclared active ingredients in dietary supplements.⁵
- 4-17-14 Hospira announced a voluntary recall of seven lots of propofol injectable emulsion following the discovery of visible metal particulate matter.⁶ The company indicated that no adverse events had been reported at the time of the recall.
- 4-18-14 Hospira announced a voluntary recall of one lot of 1% lidocaine HCl injectable following the discovery of visible iron oxide particulate matter.^{7,8}
- 4-18-14 Cubist Pharmaceuticals issued a voluntary recall of one lot of Cubicin® injectable following the discovery of visible glass particulate matter.^{9,10}
- 4-18-14 Hospira announced a voluntary recall of one lot of propofol injectable emulsion following the discovery of visible metal particulate matter.¹¹
- 4-21-14 Hospira announced a voluntary recall of one lot of 0.25% Marcaine™ injectable emulsion following the discovery of visible particulate matter and solution discoloration.¹²
- 4-23-14 The FDA announced changes in label requirements to alert patients to the possibility that epidural injections of corticosteroids to treat neck, back, and radiating pain in arms or legs could result in serious adverse events (SAEs).¹³ Though rare, these SAEs could result in vision loss, stroke, paralysis, or death. The new labeling requirement stipulates the addition of a warning to communicate these potential risks. The announcement indicated that, while the practice of injecting corticosteroids into the epidural space has been common for many years, its efficacy and safety has not been proven. As part of the agency's Safe Use Initiative, the agency has tasked a panel of experts with defining safe methods for this type of injection. In addition, the agency will convene an advisory committee later this year to further evaluate the practice.

Selected FDA Approvals

| Drug | Indication | Company |
|----------|---|-----------------|
| Tanzeum® | Tanzeum injection is a GLP-1 receptor agonist indicated as an adjunctive treatment to improve glycemic control in adults with type 2 diabetes mellitus. ¹⁵ | GlaxoSmithKline |

| | | |
|----------|---|-----------------|
| Cyramza® | Cyramza injection for intravenous infusion is a human vascular endothelial growth factor receptor antagonist indicated as a treatment for advanced gastric cancer or gastro-esophageal junction adenocarcinoma. ¹⁶ | Eli Lilly |
| Sylvant® | Sylvant is an interleukin-6 antagonist indicated for the treatment of multicentric Castleman's disease in human immunodeficiency virus (HIV)- and human herpesvirus-8 (HHV-8)-negative patients. ¹⁷ | Janssen Biotech |
| Zykadia® | Zykadia is a kinase inhibitor indicated for the treatment of anaplastic lymphoma kinase-positive metastatic non-small cell lung cancer in patients who have taken, or are intolerant to, crizotinib. ¹⁸ | Novartis |

May Advisory Committee Meetings

| | |
|--------|--|
| 5-2-14 | Nonprescription Drugs Advisory Committee ¹⁹ |
| 5-5-14 | Risk Communication Advisory Committee ²⁰ |
| 5-6-14 | Risk Communication Advisory Committee ²¹ |

May 2014 Meetings, Conferences, and Workshops

| | |
|------------|--|
| 5-8/9-14 | Public Workshop: Standards for the Interoperable Exchange of Information for Tracing of Human, Finished, Prescription Drugs, in Paper or Electronic Format ²² |
| 5-13-14 | Public Meeting on Pulmonary Arterial Hypertension Patient-Focused Drug Development ²³ |
| 5-19/20-14 | Postmarketing Requirements for the Class-Wide Extended-Release/Long-Acting Opioid Analgesics ²⁴ |
| 5-28/29-14 | Study Approaches and Methods To Evaluate the Safety of Drugs and Biological Products During Pregnancy in the Post-Approval Setting ²⁵ |

WEBLINKS

- For additional information on approvals, including labeling revisions, tentative approvals, efficacy supplements with supporting clinical data, manufacturing changes or additions, or chemistry; new strength, see <http://www.fda.gov/NewsEvents/Newsroom/default.htm>. [Link]
- For additional information on recalls, market withdrawals, and safety alerts, see <http://www.fda.gov/Safety/Recalls/default.htm>. [Link]
- For information on current drug shortages, see <http://www.fda.gov/Drugs/DrugSafety/DrugShortages/ucm050792.htm>. [Link]
- For information on drugs to be discontinued, see <http://www.fda.gov/Drugs/DrugSafety/DrugShortages/ucm050794.htm>. [Link]
- For Orange Book drug product list additions or deletions, see <http://www.fda.gov/Drugs/InformationOnDrugs/ucm086229.htm>. [Link]

¹<http://www.fda.gov/Safety/Recalls/ucm391045.htm> [Link]

²<http://www.fda.gov/Safety/Recalls/ucm393876.htm> [Link]

³<http://www.fda.gov/Drugs/ResourcesForYou/Consumers/BuyingUsingMedicineSafely/MedicationHealthFraud/ucm392814.htm> [Link]

⁴<http://www.fda.gov/Drugs/ResourcesForYou/Consumers/BuyingUsingMedicineSafely/MedicationHealthFraud/ucm234592.htm> [Link]

⁵<http://www.fda.gov/Drugs/ResourcesForYou/Consumers/BuyingUsingMedicineSafely/MedicationHealthFraud/ucm392810.htm> [Link]

⁶<http://www.fda.gov/Safety/Recalls/ucm393849.htm> [Link]

⁷<http://www.fda.gov/Safety/Recalls/ucm394020.htm> [Link]

⁸<http://www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm394026.htm> [Link]

⁹<http://www.fda.gov/Safety/Recalls/ucm393961.htm> [Link]

¹⁰<http://www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm394025.htm> [Link]

¹¹<http://www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm393904.htm> [Link]

¹²<http://www.fda.gov/Safety/Recalls/ucm394340.htm> [Link]

¹³<http://www.fda.gov/Drugs/DrugSafety/ucm394280.htm> [Link]

¹⁴<http://www.fda.gov/Drugs/DrugSafety/ucm382255.htm> [Link]

¹⁵http://www.accessdata.fda.gov/drugsatfda_docs/label/2014/125431s000lbl.pdf [Link]

- ¹⁶http://www.accessdata.fda.gov/drugsatfda_docs/label/2014/125477lbl.pdf [Link]
¹⁷http://www.accessdata.fda.gov/drugsatfda_docs/label/2014/125496s000lbl.pdf [Link]
¹⁸http://www.accessdata.fda.gov/drugsatfda_docs/label/2014/205755s000lbl.pdf [Link]
¹⁹<http://www.fda.gov/AdvisoryCommittees/Calendar/ucm393018.htm> [Link]
²⁰<http://www.fda.gov/AdvisoryCommittees/Calendar/ucm388362.htm> [Link]
²¹<http://www.fda.gov/AdvisoryCommittees/Calendar/ucm388373.htm> [Link]
²²<http://www.fda.gov/Drugs/NewsEvents/ucm388993.htm> [Link]
²³<http://www.fda.gov/ForIndustry/UserFees/PrescriptionDrugUserFee/ucm379694.htm> [Link]
²⁴<http://www.fda.gov/Drugs/NewsEvents/ucm384489.htm> [Link]
²⁵<http://www.fda.gov/Drugs/NewsEvents/ucm386560.htm> [Link]



**• Please stop by the AMWA booth to say Hi to our chapter colleagues
Kathy Boltz and Mary Stein <http://summit.stc.org/program-info/>**

**• Adobe pre-conference at STC on May 18th in Phoenix
<http://adobedayatstcsummit2014.campaignsandevents.com/>**



Annual Conference



SAVE THE DATE



DIA 2014 50th Annual Meeting Celebrate the Past - Invent the Future

June 15-19, 2014 | San Diego, CA
San Diego Convention Center



AMWA's 74TH ANNUAL CONFERENCE
OCTOBER 8-11, 2014 ★ MEMPHIS, TN



Pharmaceutical Regulatory Writing & Submissions

May 8-9, 2014 | Alexandria, VA

3rd Annual Pharmaceutical Regulatory Writing and Submissions Conference

Constructing Compliant and Comprehensive Regulatory Submission Dossiers for US and Global Health Authorities with a Thorough Understanding of Document Content Authoring Requirements, Submission Standards through to Outsourcing

May 8-9, 2014 | Alexandria, VA

<http://www.q1productions.com/conferencepost/regulatorywriting/>

AMA-zing Style — the AMA Manual of Style Column

By Dikran Toroser, PhD, Amgen Inc.

Cox Model and Regression Analyses

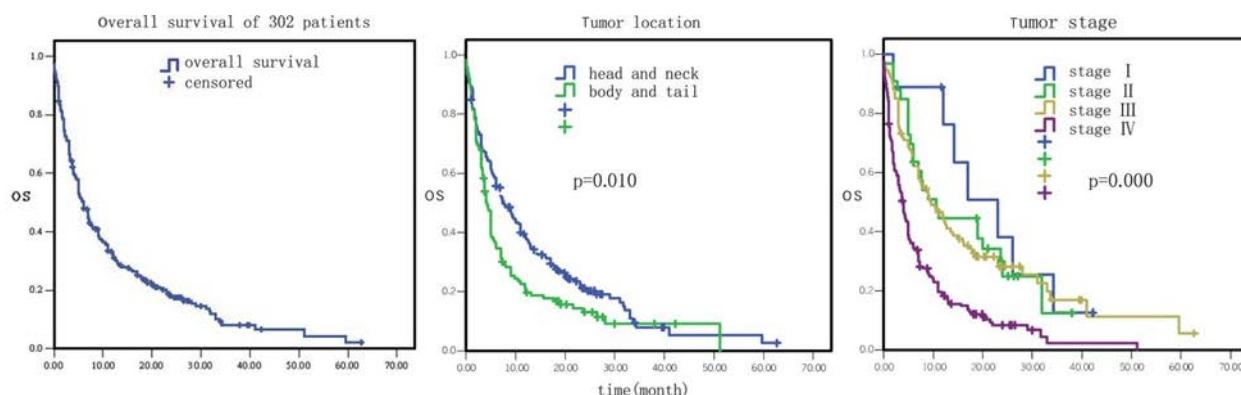
Medical writers often interact with statisticians to use complex methods to interpret equally complex datasets. Although a detailed explanation of many of these methods is beyond the scope of this column, the AMA manual contains some useful “launch-pad” statistical sections on many statistical methodologies. One of the most frequently encountered statistical methods in clinical research is the Cox model.

What is a Cox Model?

A Cox model is a method to explore the relationship between the survival of a patient and several variables.

A Cox model provides an estimate of the treatment effect on survival after adjustment for other explanatory variables. In addition, it allows estimation of the risk of death for an individual, given their prognostic variables. The risk of death is expressed as hazard (or risk) ratio.

Let's look at the example below:



These figures show survival of pancreatic cancer patients over 5 years (the higher the curve, the better is the survival). The second and third figures with multiple curves show that survival over long-term depends on tumor locations (middle figure) and tumor stages (right figure). But is this really true? Cox model can help create a smooth regression line and give us the answer by examining one factor at a time when we are confronted with multiple variables (here, tumor locations and stages.) These multiple variables that may affect survival outcome are also referred to as “explanatory variables”.

The Basics: What is Regression?

The relationship between the values of two or more variables can be described using a statistical technique called *regression*. If we study the values of two variables, X (for example, age of children) and Y (for example, height of children), we can perform a regression of Y on X. Investigating the relationship between a dependent variable (the height of children) based on the *explanatory variable* (the age of children) is an example of univariate (one variable) regression analysis.

When more than one explanatory (X) variable needs to be taken into account (for example, height of the father), the method is known as *multiple regression*.

Cox's method is similar to multiple regression analysis.

Cox models are complex—they have to be fitted using elaborate computer programs, such as SAS, STATA or SPSS. The final model from a *Cox regression analysis* usually yields an equation for the hazard (ie, the risk) as a function of several explanatory variables. Interpreting the Cox model involves examining the coefficients for each variable.

In brief, the purpose of the model is to simultaneously explore the effects of several variables on survival. Essentially, the technique allows isolation of the effects of one variable (eg, treatment) on survival from the effects of other variables. A *positive regression coefficient* for an explanatory variable usually means that the prognosis is worse and a *negative regression coefficient* implies a better prognosis for patients with higher values of that variable.

Interpretation of the Model—Noteworthy Features for the Medical Writer: The Cox model yields an equation for the hazard (risk) as a function of several explanatory variables (including the treatment; eg, the drug), which are sometimes presented in the form of tables. So how do we interpret the results presented in these tables?

The first noteworthy feature in the table is the *sign* of the regression coefficients. A positive sign (ie, positive correlation) may mean that the hazard (risk of death) is higher and thus the prognosis worse for subjects with higher values of that variable.

The second noteworthy feature is the *P-value*; is it significant? If it is not statistically significant, and the 95% confidence interval for the hazard ratio includes 1, then there may be no difference in survival. In short, using these outputs, the authors are trying to determine whether there is a significant difference in overall survival between treatments, even after adjustment for relevant prognostic factors.

Also see page 864 of the AMA Manual of Style 10th edition for a definition of a Cox model.

Further Reading:

Walters SJ. What is a Cox model? [Monograph] Published by Hayward Medical Communications, a division of Hayward Group Ltd. May 2009. Available at:

http://www.whatissseries.co.uk/whatis/pdfs/What_is_Cox_model.pdf

Acknowledgement: Thanks are due to Ajay Malik, PhD, especially for insights on Cox analysis in cancer.

Footnote: The Figure on pancreatic survival is from Zhang et al 2011 (doi: 10.3892/etm.2011.412). Available at:

<http://www.spandidos-publications.com/etm/3/3/423>

Meeting Report

By Donna Simcoe (Cadence Pharmaceuticals Inc) and Dikran Torosser (Amgen Inc)

The International Society of Medical Publication Professionals (ISMPP) celebrated their 10th annual meeting this month among the cherry blossoms of Arlington with ~400 registered attendees. ISMPP is a non-profit organization with over 1,300 members involved in the publication of medical research, including pharmaceutical, biotechnology, and device companies, medical publications and communications agencies, medical journal publishers and editors, and professional medical writers.

Medical writing was a topic of a few sessions and posters. Research performed by Joanna Bloom of Envision Pharma Group investigated professional medical writing articles in biomedical journals and popular press and found that negative articles about ghostwriting are in the decline. Common themes in positive articles stated that professional medical writers are not ghostwriters, professional medical writers collaborate ethically with authors and ensure their contributions are accurately disclosed, and that professional medical writers are essential for timely and accurate dissemination of clinical trial data and other medical information. Multiple case studies and insights were presented during preconference workshops on ethics, alternative publication media and the Sunshine Act.

Some additional medical writing/publication related updates from the meeting were: Global Publication Survey (GPS) manuscript is now accepted and will contain 31,000 pertinent data-points from publication professionals, including input from industry as well as freelancers. The much awaited Good Publication Practices 3 (GPP-3) manuscript, updating the previous GPP-2 publication, is under development with a plan for publication in 2015.

Grace Lee et al at Scientific Therapeutics Information researched 180 infectious disease or general medicine journals and found that medical writing

support was acceptable to the majority of journals that disclosed their policies, however, approximately one third of journals did not clearly state policies on medical writing support.

A poster by Tamzin Gristwood of Oxford PharmaGenesis outlined the results of a survey regarding listing medical writers as authors on publications. Of the 155 respondents, 60% were medical writers and the rest were other publication professionals. The proportions of respondents believing that medical writers should always, frequently, occasionally or never be listed as authors were: 34%, 31%, 22% and 6% for systematic reviews, 22%, 28%, 26% and 14% for narrative reviews, and 18%, 14%, 36% and 25% for primary research manuscripts, respectively.

Disha Dayal of Cactus Communications researched the trends in the acknowledgement of professional medical writers in lymphoma clinical trial publications in the past 10 years. Of the 1360 articles, 151 (11.1%) acknowledged medical writers, of whom 46 (30.46%) were employed by professional agencies. An approximate 3-fold increase in medical writer acknowledgment was observed over the last 10 years (2004, 7.14%; 2013, 20.37%).

The new ISMPP mission “Advance the medical publication profession globally through enhanced

integrity & transparency in medical publications, improve standards, best practices, advocacy & professional collaborations" was presented to close the meeting.

Overall, the ISMPP meeting was a huge success.



de-MS-tifying Word

By Susan Chang, PhD, Susan Chang Consulting

Creating Redline Drafts

Sometimes writers need to keep a “running” redline draft to show revisions over the course of document development. These tips explain how to maintain a redline draft showing old versus new revisions and how to show in-text revisions with specific formatting. Images and instructions are for MS Word 2007/2010 (PC), but these concepts apply to any version of Word.

0 – Before You Begin: Set options for the track changes function.

My preferred track change options are shown here. Note that these instructions do not include tracking of format changes, table cell highlighting, or text moves. I typically turn these features off.

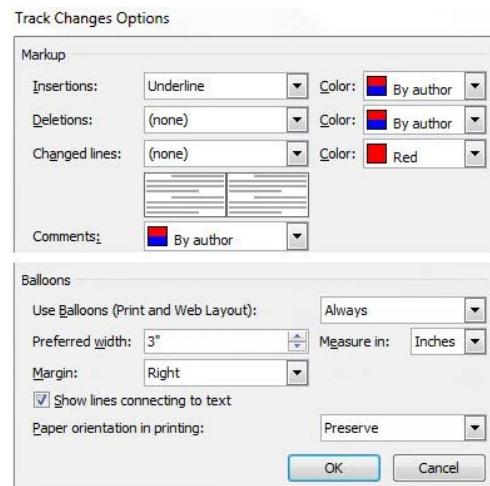
Review tab → Track Changes → Change tracking options...

...→ Uncheck Track moves

...→ Uncheck Track formatting

...→ Set all table cell highlighting to “(none)”

...→ Adjust other options as shown:



1 – First Revision: Set tracked changes username and initials.

Choose a primary user name for your document.

Review tab → Track changes → Change user name → User Name [Susan Chang] / Initials [SChang.]

Until recently, most medical communicators have entered the field from other professions such as journalism, medicine, laboratory research, pharmacy, and education. A 2007 survey showed that just 4% of members in the American Medical Writers Association (AMWA) have an academic degree in medical or technical writing. However, in the last decade, educational institutions have begun offering degrees and certificates in medical communication. As a result, more and more graduates will start their careers as medical communicators.

Comment [SChang.1]:
What was actually measured here?
4% have a degree in writing ONLY,
or could this be an additional degree?
Deleted: AMWA

2 – Second Revision: Change tracked changes username and initials.

Change your user name to reflect new changes. Remember to inform reviewers that all changes since the previous review are tracked in a different color to facilitate their review.

Review tab → Track changes → Change user name → User Name [New Change] / Initials [NewChange]

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Comment [SChang.1]:
What was actually measured here?
4% have a degree in writing ONLY,
or could this be an additional degree?
From Bob: Leave text as is.
Deleted: AMWA
Deleted: in the last decade.
Comment [NewChange2]:
Jill – Should this be hyperlinked?

3 – Final Redline Options: Change specific formatting for insertions & deletions.

You can make all insertions/deletions look like they are from the same author by changing the “Markup” options on the track change menu (change all to “black”). You can also create an “in line” tracked changes by changing other formatting options. Note that comments have been removed in this example text.

Review tab → Track Changes → Change tracking options...

...→ Markup → Set Insertions to bold / black; set Deletions to strikethrough / black

...→ Balloons → Never (This will give you in-line insertions and deletions.)

Until recently, most medical communicators have entered the field from other professions such as journalism, medicine, laboratory research, pharmacy, and education. A 2007 survey showed that just 4% of AMWA members **in the American Medical Writers Association (AMWA)** have an academic degree in medical or technical writing. However, **many** ~~in the last decade,~~ educational institutions have begun offering degrees and certificates in medical communication. As a result, more and more graduates will start their careers as medical communicators.

Refer to www.AMWA.org for a list of such programs.

Reminders:

- Remember to change your username, initials, and track change options back to your preferred settings for other documents.
- Track change options can be altered by other users; the only way to make the visual effects described above “permanent” is to create a PDF rendering of the document.
- If the Word document itself truly must have all tracked changes coming from one user, then you can redo all changes with your primary preferred user name. This method can be painful, but it can also help you keep track of what has and has not been incorporated/addressed.

Word woes?

Email me at SKC@SusanChangConsulting.com

Social Brunch Meeting of the Arizona Satellite Chapter

Report By Scott Harrington, PharmD, RPh, New AMWA member

It was an engaging two hours together in a most serene resort restaurant known as T. Cook's, located toward the eastern outskirts of Phoenix. I enjoyed sharing the trip up from Tucson with fellow member Mary Kay Stein.

Members of the AMWA Arizona Satellite Chapter gathered in elegant 'round-table' style for a stimulating and informative conversation. As a new AMWA member who is in the process of returning to medical writing from the clinical pharmacy arena, I was eager to discover what kinds of interesting people I would meet. The event did not disappoint: There were seven attendees, five women and two men, all very dynamic with intriguing stories of their own, along with an eagerness to hear about each others' background.

Among us were four independent writers, along with three others employed in such diverse organizations as Ethos Health Communications, Scottsdale Healthcare, and the Mayo Clinic. Two members related their experiences in oncology writing: one employed with Mayo Clinic, the other, an independent writer coming originally from a cancer biology research-oriented background. Another of the independent writers came to medical writing from the field of journalism, and has served as long-time managing editor of a newsletter related to eating disorders. Lastly, there was also one pharmacist in the group, a former pharmacology textbook author who hopes to re-enter the field as a freelance medical writer. Oh, and lest I forget, our most energetic coordinator, Dr. Kathy Boltz, wowed the rest of us with her newfangled technological miracle, the "Smart Pen". Yes, I said "Smart Pen"! This device actually uses a special high-tech paper that allows the pen to electronically transcribe your handwritten notes, and even ambient spoken word, into your computer device (pad, etc.). But don't forget to turn it "on" first!

Finally, I received much encouragement as well as several helpful "newbie" suggestions for re-entering the medical writing field. In summary, it was an intriguing and lively conversation, and I was reminded, as a new member, of how friendly and collaborative AMWA members can be.

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Drscott85710@gmail.com



AMWA Chapter members, Scott Harrington, Mary Stein (seated), Colleen Duffy, Mary Ann Clifft, Joseph Gass (seated), and Alison Davis, and Kathy Boltz (not in picture).

Picture courtesy of Kathy Boltz

May 2014 Job Listing Synopsis

Contract Medical Writer

Biophase Solutions; San Diego & Los Angeles, CA

Senior Manager Medical Writer

Orexigen; San Diego, CA

As a reminder, complete Job Listings are available for current, interested members and are available through the following ways:

- Job openings are sent out ~monthly through the jobs mailing list
- Job listings will be posted periodically through our LinkedIn SubGroup, AMWA Pacific Southwest Chapter, so be sure to join the group

Please e-mail employment-coordinator@amwa-pacsw.org if you'd like to receive job listings or share any job leads with the group and it will be added to the job listings.



Space Shuttle Discovery: Up, Close and Personal



Space Shuttle Discovery at Smithsonian Museum, Washington, DC.
Picture by Kathy Boltz.

Last month, Kathy Boltz attended AMWA Spring Board of Directors Meeting in Bethesda. And while she was in the National Capital, she took some time out to visit Smithsonian Air and Space Museum, got really close to the historic and storied shuttle Discovery and sent us a postcard.

Here are eight fun facts about the Shuttle Discovery:

1. Flew 39 missions from 1984 to 2011
2. Logged 365 days and 148+ million miles in space (both shuttle records)
3. Launched Hubble telescope
4. Launched first female shuttle pilot & commander Eileen Collins
5. Launched first Russian to ride a US spacecraft (Sergei Krikalev in 1994)
6. Launched John Glenn into orbit, who at age 77 became the oldest person ever to reach space. John was the graduate of the first ever astronaut class (Mercury Seven) chosen in 1959 and was the first American to orbit earth in 1962
7. Was the first shuttle to return to orbit after Challenger as well as after Columbia disasters
8. Was named after two historic oceangoing exploration ships: one explored northwest passage between Atlantic and Pacific oceans in 1610; and, the second under Captain James Cook discovered Hawaiian islands in the 18th century.



Picture Credit: NASA
<http://www.nasa.gov/centers/kennedy/shuttleoperations/orbiters/discovery-info.html>

Sources:

[Space.com](http://www.space.com/15327-space-shuttle-discovery-10-cool-facts.html) (<http://www.space.com/15327-space-shuttle-discovery-10-cool-facts.html>, <http://www.space.com/15330-space-shuttle-discovery-5-surprising-facts.html>); [Wikipedia](http://en.wikipedia.org/wiki/Space_Shuttle_Discovery). http://en.wikipedia.org/wiki/Space_Shuttle_Discovery, [NASA](http://www.nasa.gov/centers/kennedy/shuttleoperations/orbiters/discovery-info.html).
<http://www.nasa.gov/centers/kennedy/shuttleoperations/orbiters/discovery-info.html>

—Editor